Policy and Procedures for Prescribing Synagis
RSV Season 2006-2007

For the upcoming RSV season, Synagis will not require prior approval (PA) for NC Medicaid recipients. However, the responsibility for appropriate usage of Synagis will be placed on prescribers and pharmacy providers. The clinical criteria utilized in this policy are consistent with currently published American Academy of Pediatrics guidelines (http://aappolicy.aappublications.org/cgi/content/full/pediatrics; 112/6/1442). Please ensure that the person completing the Synagis criteria form has verified that the conditions exist and are accurate. If a patient does not fit the published criteria and you still wish to prescribe Synagis, you must submit your request to DMA on the *Request for Medical Review for Synagis Outside of Criteria* form and fax the request to DMA at **919-715-1255**.

NC Medicaid will begin coverage of Synagis October 15, 2006. During the season, **no more than five (5) monthly doses of Synagis can be obtained by using these forms. The number of doses should be adjusted if an infant received the first dose prior to a hospital discharge.** Delays in getting a request processed can occur if the patient does not have a Medicaid identification number or the form is not complete.

The criteria form must be signed by the prescriber and submitted to the pharmacy distributor of choice. The criteria form must be maintained at the pharmacy distributor's location. The pharmacy distributor must mail a copy of the submitted forms weekly to DMA. Please mail submitted forms to:

NC Division of Medical Assistance
Pharmacy Program
1985 Umstead Drive
2501 Mail Service Center
Raleigh, N.C. 27699-2501

Pharmacy distributors who do a large volume of Synagis claims are asked to submit information supplied on the criteria forms on a diskette. Please call Charlene Sampson at (919) 855-4306 to coordinate this process.

The Request for Medical Review for Synagis Outside of Criteria form must be signed by the prescriber and faxed to DMA at 919-715-1255. A copy of the approval letter must be maintained at the pharmacy distributor's location. Please refer to the following guidelines when submitting a request:

- **For the following four diagnoses, DOB must be on or after 10/15/04:**

  Chronic Lung Disease of Prematurity (Bronchopulmonary Dysplasia)

  The infant has Chronic Lung Disease (bronchopulmonary dysplasia) and has necessitated treatment (supplemental oxygen, bronchodilator, diuretic, corticosteroid) in the six months before the start of the season.

Hemodynamically Significant Congenital Heart Disease

Infants less than 12 months of age who are most likely to benefit include those receiving medication to control CHF, moderate to severe pulmonary hypertension, and/or cyanotic heart disease.

Infants NOT at increased risk from RSV who generally should NOT receive immunoprophylaxis include: hemodynamically insignificant heart disease such as secundum atrial/septal defect, small VSD, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, PDA, lesions adequately corrected by surgery unless the infant continues on medication for CHF, mild cardiomyopathy where the infant is not receiving medical therapy.

Cystic Fibrosis

The infant has Cystic Fibrosis and either requires chronic oxygen or has been diagnosed with nutritional failure.

Severe Congenital Immunodeficiency

Severe combined immunodeficiency disease or severe acquired immunodeficiency syndrome.

- **Infant is born at an EGA of:**

  ≤ 28 weeks and DOB is on or after 10/15/05
  29-32 weeks and DOB is on or after 4/15/06

- **If born between 32 weeks and 1 day and 35 weeks and 0 days gestation, must be less than 6 months of age (DOB on or after 4/15/06) at the start of the season and have two or more defined risk factors:**

  - School-age Siblings
  - Attends Day Care
  - Severe Neuromuscular Disease
  - Exposure to prolonged wood burning heaters which are the primary source of heat for the family. Tobacco smoke is NOT a risk factor because it can be controlled by the family.
  - Congenital abnormalities of the airways.

- **Request for Medical Review for Synagis Outside of Criteria**

  This form will be used for patients who do not explicitly meet the guidelines whose providers still wish to prescribe Synagis. Please fill out the requested information and fax to DMA at **919-715-1255**. PLEASE NOTE THAT THIS IS THE ONLY FORM THAT **PRESCRIBERS** SHOULD FAX TO DMA.